

From: ErrorTracker
Sent: Wed 10/22/2003 10:22 AM
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Cc:
Subject: ACKNOWLEDGEMENT OF REQUEST FOR CORRECTION: FOR RFC#13166

Thank you for your request for correction under the Environmental Protection Agency's Information Quality Guidelines dated 10/16/2003. Your request was received in this office on 10/20/2003 and has been forwarded to the appropriate organization within the Agency.

REPORTED REQUEST FOR RFC #: 13166
Request for Correction: "TECHNICAL REVIEW OF DIISONONYL PHTHALATE, CAS NO. 028553-12-0, 071549-78-5, 014103-61-8, 068515-48-0, OFFICE OF ENVIRONMENTAL INFORMATION, ENVIRONMENTAL ANALYSIS DIVISION, ANALYTICAL SUPPORT BRANCH, AUGUST 2000", AND STATEMENTS REGARDING, AND CONCLUSIONS BASED ON, THAT TECHNICAL REVIEW CONTAINED IN EPA'S RULEMAKING PROPOSAL TO ADD SUCH CHEMICALS TO THE TOXICS RELEASE INVENTORY, 65 FED. REG. 53681 ET SEQ., SEPT. 5, 2000 (DOCKET CONTROL NUMBER OEI-100004).

Compliance with IQGs: DIISONONYL PHTHALATE ("DINP"), A CATEGORY OF THREE ESTERS, IS A CHEMICAL WHICH IMPARTS FLEXIBILITY TO A MULTITUDE OF PLASTIC (PRINCIPALLY PVC) PRODUCTS FOR THE CONSUMER, CONSTRUCTION, AND MANUFACTURING SECTORS. SUCH PRODUCTS INCLUDE VINYL FLOORING AND WALL COVERING, VINYL-COATED FABRICS, GLOVES, TUBING, SHOES, SEALANTS, AND ELECTRICAL INSULATION.[1]

THE PRELIMINARY DINP TECHNICAL REVIEW OF AUGUST 2000, AND THE SUBSEQUENT SEPTEMBER 5, 2000 RULEMAKING PROPOSAL TO ADD THE DINP CATEGORY TO THE TOXICS RELEASE INVENTORY ("TRI"), ARE NOW MORE THAN THREE YEARS OLD, BUT ARE STILL BEING DISSEMINATED AS A SOURCE OF INFORMATION ON DINP. AS DISCUSSED IN DETAIL BELOW, THE PRELIMINARY TECHNICAL REVIEW AND NPRM (HEREAFTER REFERRED TO TOGETHER AS THE "REVIEW") DO NOT MEET THE DATA QUALITY STANDARDS WHICH WERE ISSUED AFTER THEIR RELEASE. THE REVIEW CONTAINS SUBSTANTIAL OMISSIONS OF DATA AND ANALYSIS, INCLUDING SIGNIFICANT NEW DATA AND PERTINENT CONSENSUS SCIENTIFIC VIEWS WHICH HAVE BEEN PUBLISHED SINCE AUGUST 2000[2], BIASED CONCLUSIONS WHICH ARE NOT CONSISTENT WITH THE TRI LISTING REQUIREMENTS, INACCURACIES, AND RELIANCE ON TRI LISTING GUIDANCE WHICH ITSELF CANNOT MEET DATA QUALITY STANDARDS.[3] (PLEASE SEE ENTIRE RFC, IN AN EMAIL RECEIVED BY EPA ON 10/20/2003.)

Recommendation: 1. EPA SHOULD WITHDRAW THE CURRENT REVIEW.
2. IF EPA INTENDS TO PROCEED WITH THE LISTING PROPOSAL, IT SHOULD

FIRST REVISE THE REVIEW TO BRING IT INTO COMPLIANCE WITH THE DATA QUALITY STANDARDS BY:

INCLUDING AND DISCUSSING THE DATA NOT CONSIDERED AND EVALUATED WHICH IS SPECIFIED ABOVE, PARTICULARLY THE PRIMATE STUDIES, AND EXPOSURE/DOSE AND PHARMACOKINETIC DATA, AND EVALUATION OF THEIR IMPLICATIONS FOR HUMANS AS OPPOSED TO LABORATORY ANIMALS;

MAKING ALL DETERMINATIONS IN ACCORDANCE WITH THE STATUTORY STANDARD OF "REASONABLY ANTICIPATED" TO CAUSE ADVERSE HEALTH EFFECTS "IN HUMANS" (AS OPPOSED TO "MIGHT"); AND

REMOVING BIAS DUE TO USE OF POLICY-DRIVEN DEFAULT ASSUMPTIONS. ANY AMENDED REVIEW SHOULD BE SUBJECT TO A NEW OPPORTUNITY FOR PUBLIC COMMENT.

2. IF EPA DECIDES TO PRODUCE A NEW AND DATA QUALITY-COMPLIANT REVIEW, IT SHOULD SUBJECT THE NEW REVIEW DOCUMENT TO EXTERNAL PEER REVIEW TO ENSURE ITS ACCURACY, COMPLETENESS, AND OBJECTIVITY, AND TO ENSURE THAT IT COMPLIES WITH NEW OMB DATA QUALITY GUIDANCE ON PEER REVIEW.

3. EPA SHOULD UNDERTAKE A NEW RULEMAKING TO CLARIFY ITS 1994 TRI LISTING GUIDANCE WITH REGARD TO HOW A "RELATIVELY LOW" OR "MODERATE" DOSE IS DETERMINED BEFORE ISSUING, OR DECIDING WHETHER TO ISSUE, EITHER A NEW REVIEW OR ANY FURTHER RULEMAKING ACTION ON DINP.

4. IF EPA STILL PROPOSES, AFTER THE ABOVE ACTIONS, TO CONTINUE TO PROPOSE TRI LISTING OF DINP, IT SHOULD ISSUE A NEW NPRM BASED ON THE REVISED REVIEW.

Impact: EPA IS CONTINUING TO DISSEMINATE THE DINP REVIEW WITH ALL OF ITS DEFICIENCIES, AND ACTIVIST GROUPS AND OTHERS CONTINUE TO REFER TO IT AS A BASIS FOR PROMOTING TERMINATION OF USE OF DINP.[13] (PLEASE SEE ENTIRE RFC, IN AN EMAIL RECEIVED BY EPA ON 10/20/2003.)

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The Environmental Protection Agency's goal is to respond to requests within 90 days of receipt. In the meantime, if you have any questions regarding the Information Quality Guidelines or the Request for Correction process, please visit the EPA Information Quality Guidelines site (www.epa.gov/oei/qualityguidelines/index.html) or send a

letter or fax or e-mail to our office at the address noted below.
Please include the Request Number stated in the reference line of
this letter in all correspondences.

Sincerely,

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